AUG - 5 1996

Mr. E. Charles Brice
Kemin Foods, L.C.
2100 Maury Street, Box 70
Des Moines, Iowa 50301-0070

Dear Mr. Brice:

This is in response to your letter of July 9, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your product FloraGLO™.

> Lutein and zeaxanthin are the only carotenoid antioxidants found deposited in the lens and macular region of the eye to absorb harmful blue light. They may serve to protect the macular region from light induced damage or other oxidative insults.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended for one of these purposes, in that it claims that lutein and zeaxanthin absorb harmful blue light and may serve to protect the macular region from light induced damage or other oxidative insults. This claim evidences that it is intended to prevent eye damage. Thus, the product is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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